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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
600 GALLERIA PARKWAY
STE 1500
ATLANTA, GA 30339

EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,825	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 132-134,136,138,140,147,149,152,154,156,157,160,163,173,176,177,180,188,189,191,195,198-200,202,204,207-210,213,214,217,218,220,221,227-238,240,241,243,245,246,260,268 and 269.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 135,139,146,148,153,168-172,178,179,183,196 and 197.

Continuation of Disposition of Claims: Claims rejected are 132-134,136,138,140,147,149,152,154,156,157,160,163,173,176,177,180,188,189,191,195,198-200,202,204,207-210,213,214,217,218,220,221,227-238,240,241,243,245,246,260,268 and 269.

DETAILED ACTION

Claims Under Examination

An action on the merits of claims 132, 133, 134, 136, 138, 140, 147, 149, 152, 154, 156-157, 160, 163, 173, 176, 177, 180, 188-189, 191, 195, and 198-200, 202, 204, 207-210, 213, 214, 217-218, 220-221, 227-238, 240-241, 243, 245-246, 260, 268-269 follows, as they read upon the elected Specie A (claim 134), Specie B (claim 140), Specie C (claim 147), Specie E (claim 154). This application contains claims 135, 139, 146, 148, 153, 168, 169, 170-172, 178-179, 183, and 196-197 drawn to an invention nonelected with traverse in the response filed 09/13/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-131, 137, 141-145, 150-151, 155, 158-159, 161-162, 164-167, 174-175, 181-182, 184-187, 190, 192-194, 201, 203, 205-206, 211-212, 215-216, 219, 225-226, 239, 242, 244, 247-259, 261-267 are cancelled.

Information Disclosure Statement

The information disclosure statement filed 05/15/2007 has been considered in full.

Priority

Priority to US Provisional Applications 60/456,271, filed 3/19/2003 and 60/532,487, filed 12/26/2003, and 60/543,576, filed 2/11/2004 has been acknowledged.

Withdrawn Rejections

The rejection of claims under 35 U.S.C. 101 for non-statutory subject matter is withdrawn in view of applicant's amendments to the claims, filed 09/06/2007.

The rejection of claims 132, 133, 141, 142, 144, 147, 150, 154, 156, 157, 158, 161, 163, 164, 173, 174, 175. 176, 192-195, 201, 202, 204, 205, 206, 207, 209, 210, 213, 216, 234, 236, 237, 242, 243, 244, 245-247, 258, 259, 263, and 266-268 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendments to the claims, filed 09/06/2007.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132, 133, 134, 136, 138, 140, 147, 149, 152, 154, 156-157, 160, 163, 173, 176, 177, 180, 188-189, 191, 195, and 198-200, 202, 204, 207-210, 213, 214, 217-218, 220-221, 227-238, 240-241, 243, 245-246, 260, 268-269 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that depend directly or indirectly from claim 132 are also rejected herein due to said dependency. *The following rejections are necessitated by amendment.*

Claim 132 recites a method "for periodically adjusting a diabetic patient's insulin dosing therapy...", which is an intended use. The claim does not recite any active method steps. All the limitations recited in the claim are directed to the intended use of the claimed method.

Therefore, claim 132 is indefinite in that it fails to point out what active method steps are required to practice the claimed invention. As a result, it is unclear in what way a diabetic patient's insulin dosing therapy is periodically adjusted.

Claim 132 (p.3, lines 3-4) recites "one of the two components of the change for Prescription Insulin." There is lack of antecedent basis for this limitation. As a result, it is unclear what two components constitute the change for Prescription Insulin.

Claim 269 recites the formula "{an adjusted Carbohydrate-to-Insulin Ratio for a given time interval} equals {amount of carbohydrate in the previous given time interval} divided by {{Meal Insulin in the previous given time interval} plus {the change for Total Daily Prescription Insulin} multiplied by {Corrective Insulin in the previous given time interval} divided by {total daily Corrective Insulin in the previous given time interval} minus {{adjusted Basal Rate in the given time interval} minus {Basal Rate in the previous given time interval}} times {duration of the given time interval}}." As written, applicant's use of parentheses does not clarify which element(s) of the instant formula are subject to multiplication, division, addition, and/or subtraction. Clarification is requested via amendment of the claims to recite an actual equation comprising variables, wherein the variables are defined.

Claim Rejections- 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 132, 133, 134, 136, 138, 140, 147, 149, 152, 156, 157, 189, 191, 198, and 199 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kaufman et al. (Diabetes Metab. Res. Rev., 1999, Vol. 15, p.338-352).

Kaufman et al. teach a method for adjusting an insulin dosing schedule for an insulin pump based on basal rates, carbohydrate bolus doses, correction bolus based on meals, and corrective insulin dosages based on blood sugar testing and time intervals (daily and hourly) [Table 4], [Table 5], and [p.343, Col. 2, ¶ 2]. More specifically, Kaufman et al. also teach the following aspects of the instant claims:

- Guidelines and formulas for determination of new insulin values based on meals (i.e. carbohydrates) and correction of blood glucose levels outside a target range [p.344, Col. 2, ¶ 2] and corrective insulin dosages based on blood glucose testing algorithms for adjusting basal and bolus insulin regimens based on changes in blood glucose levels [p.344, Col. 1, Table 7].
- Calculating the subcutaneous insulin dosage history, calculating an amount of insulin per carbohydrate (i.e. carbohydrate to insulin ratios), at dawn (i.e. rising from sleep), elevated blood glucose level, basal and bolus ratios [Table 6] and at different time intervals [Table 5] and [Fig. 4].
- Insulin pump devices with downloadable cradle that do not provide for memory of carbohydrate amounts [Fig. 3].
- Corrective insulin dose changes based on input of pre-meal times, basal dosages, and blood sugar levels, and subtraction of values [Fig. 4].
- Insulin dosage scheduling based on exercise [Table 5].
- User input of the Total Day's meal insulin [Table 6]. It is noted that the claims recite that

preliminary estimated change for total day's meal insulin is input by a user or estimated by "BoTFbK".

- Two modes of insulin delivery [p.340, Col. 1, The basics of CSII] are provided including basal infusion, and periodic adjustment through bolus insulin delivery. The basal infusion rates are preprogrammed and can automatically change throughout the day and night to meet known alterations in insulin requirement.
- Outputting dosage information to a display [Fig. 4].

Response to Arguments

Applicant's arguments, filed 09/06/2007, that Kaufman et al. do not teach or suggest the adjustment of parameters, for example the adjustment of the carbohydrate-to-insulin ratio (CIR) parameter, or the calculation of new CIR's that are customized to apply to the individual patient have been fully considered but are not persuasive. Kaufman (p.344, Col. 2, ¶1) shows calculating carbohydrate to insulin ratios (CIR) and adjustment of CIR by division (Table 6, step 5), which is a teaching for adjustment of the CIR. Kaufman also shows adjusting rules for calculation (p.344, Col. 2, ¶2) based on age, duration of disease, and amount of prior insulin dosage, and adjustment algorithms (Table 7) that take into account patient age and insulin dosage for determining correction dosages for patients. This rejection is therefore maintained.

Claims 132, 133, 134, 136, 138, 140, 160, 177, 180, 188, 195, and 200 are rejected under 35 U.S.C. 102 (e) as being anticipated by Galley et al. (US 2003/0028089, Filed Jul. 31, 2001).

Galley et al. teach a diabetes management system comprising an insulin delivery unit, a control unit, and a glucose sensor, for determining corrective insulin dosages when predictive

glucose values lie outside of pre-determined ranges for calculating precise amounts of insulin required to keep a user's blood sugar concentration at a previously set target [Abstract]. More specifically, Galley et al. teach additional intervention boluses (i.e. additional dosage) and delivered insulin in response to blood glucose values (i.e. corrective doses) [Fig. 5] and [0026]. Galley et al. also provide means for blood glucose testing and blood sample collection [0028]. Galley et al. also teach feed-back and feed-forward algorithms and equations for calculating insulin dosages based on carbohydrate-to-insulin ratios, scaling factors, total insulin dosage, carbohydrates, insulin-to-carbohydrate ratio, and linear fit intercept values (i.e. statistical correlation values) [Fig. 7], [0009], and [0063-0069]. Galley et al. also teach infusion rate constraints based on fractional values (β) and basal rates [0070-0072]. Galley et al. also teach a feedback algorithm expressed as a function of basal insulin, normalized insulin values (i.e. ratios), meal-related insulin doses, recommended insulin doses, target blood glucose values, sensitivity factors, time intervals between insulin cycles [0034] and [0040-0055], and related summation equations [p. 4, Col. 2, Equations 1, 2, and 3]. Galley et al. also teach user-input carbohydrate amounts, meal types, and glycemic indexes [0069], and infusion rates (i.e. derivate) [0070]. Galley also teaches a control unit that transmits (i.e. outputs) a corrective amount to the delivery unit [0004] and a predictive model (i.e. preliminary estimation) based on the following equation: .DELTA.G=-(TotalInsuRemain-BasalReq)*Sensitivity, wherein DELTA.G = future change in glucose level at a pre-determined time, TotalInsuRemain = amount of insulin remaining in the subject's system at the current time, BasalReq = how much insulin the subject is estimated to need at the pre-determined time, and Sensitivity = Insulin sensitivity [0004].

Response to Arguments

Applicant's arguments filed 09/06/2007 that Galley et al. do not teach a provision for adjusting the correction factor (CF) or the CIR have been fully considered but are not persuasive. Galley et al. show [0009] a system for recommending insulin dose that compensates for carbohydrates in a subject comprising a feedforward algorithm that adjusts CIRs by meal dependent scaling factors (i.e. CF) [0063-0069] that are dependent on user-input of carbohydrate amounts and meals. Therefore this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 132, 133, 134, 136, 138, 140, 147, 149, 152, 160, 177, 180, 188, 195, 200, 208-210, 241, 244, 260, and 268 are rejected under 35 U.S.C. 103(a) as being made obvious by Albisser et al. (Medical & Biological Engineering & Computing, 1986, Vol. 24, p.577-584), in view of Ribeiro (US 2003/0055570, Filed Aug. 28, 2001).

Albisser et al. teach a method for adjusting insulin dosages comprising new insulin dosage values derived from iterative basal insulin dosages (both before and after meals), wherein dosages are administered over days and are adjusted using blood glucose test results coupled with additional multiplying factors [p.578, Col. 1, ¶ 4 and Col. 2]. More specifically, Albisser et al. also teach the following aspects of the instant claims:

- Insulin injected dosages fixed (i.e. basal insulin) and then adjusted over time in response to meals (i.e. meal insulin) [Fig. 3] and [p.581, Section 3.1.3], wherein adjusted (i.e. corrective) insulin dosages (IAID, IAIB, SAIB, SAID) are calculated based on patient blood glucose information, carbohydrates, and effects are measured according to blood glucose tests [p.578, Col. 1, ¶ 4 and Col. 2]. As this is an iterative algorithm, the above process is an inherent teaching for the calculation of "new" mean insulin values.
- Iterative feedback algorithm and equations for adjustment of insulin dosage values based on the addition/subtraction of quotient comprising the Σ of glucose values, sensitivity factors (i.e. correction factors), plasma levels based on food intake, insulin dosages values from the previous day (i.e. old values), successive dosing cycles, ratios, and days [p.578, Equations 1-4].
- Treatment scenarios for patients based on expert practitioner prescribed dosages and computer simulated dosages before and given time intervals, and statistical comparison (i.e. change) [Table 1, Table 2, and Fig. 3].
- Daily dosage adjustment using the insulin dosage computer algorithm [Section 3.1.3, p. 581]
- User information comprising glucose levels with upper and lower boundaries based on future carbohydrate amounts ingested after meals [Table I and II].

Albisser et al. do not specifically teach limitations directed to "carbohydrate-to-insulin ratios" and "blood concentration targets". However, Albisser et al. do teach methods for measuring blood glucose levels during meals and related insulin rates, as set forth above, which makes obvious the use of carbohydrate-to-insulin ratios, as required by the instant claims..

Ribeiro teaches a method and computer system for calculating precise amounts of insulin required to keep a user's blood sugar concentration at a previously set target [Abstract] and [0100] and [Fig. 1 and 2]. Ribeiro also teaches the following aspects of the instant claims: a method and device for determining subject's blood sugar level, amount of carbohydrates, amount of insulin forecasted in a single day, and calculating appropriate amount of insulin based on sugar level, carbohydrates, and forecast amount of insulin [Ref. Claim 132]; insulin-carbohydrate ratios (i.e. old and new), pre-meal and post-meal blood sugar levels (i.e. target and measured), and insulin sensitivity [Ref. Claim 4]. Ribeiro makes obvious the plurality of user-entered variables and equations for calculating total daily insulin amounts, blood sugar readings set by the physician and user as targets, quantity of carbs, bolus values, insulin ratios, carbohydrate ratios, standard deviation values from target, insulin per day values [Figs. 4, 5, 6, and 9] and [0035-0071].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the insulin dosage adjustment algorithm taught by Albisser et al, by incorporating the additional parameters and equations for insulin bolus calculation taught by Ribeiro, where the motivation would have been to improve conventional insulin therapy and short-acting insulin dosages [Ribeiro, Section 0118] with respect to the art-recognized method of estimating a patient's insulin sensitivity and insulin dosage based upon factors such as pre-meal and post-meal blood sugar levels, carbohydrate content, and timing of dosage, as provided by Ribeiro, resulting in the practice of the instant claimed invention. One of skill in the

art would have had a reasonable expectation of successfully combining the method of Albisser et al. with the calculation program of Ribeiro as both teach methods for insulin dosage and blood glucose monitoring.

Response to Arguments

Applicant's arguments filed 09/06/2007 that Albisser et al. do not use amounts of carbohydrates or calculate a carbohydrate-to-insulin ratio (CIR), and that Ribeiro et al. do not teach Basal Rate. The Examiner acknowledged that Albisser et al. do not teach CIR calculations. Albisser et al., however, do show (See: Fig. 3 and p.581, Section 3.1.3) insulin injected dosages adjusted over time in response to meals (i.e. meal insulin) and show (p.579, Col. 1) changes in insulin dosages prescribed based on glucose levels measured based on time and meal consumption levels during meals and related insulin rates, which makes obvious the use of carbohydrate-to-insulin ratios. Ribeiro et al. was relied upon as a teaching for CIR calculations, and not Basal Rates. This rejection is therefore maintained.

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 155-157, 158-162, 164-167, 174-175, 177, 180-182, 189-195 198, 199, 200-201, 203, 205, 209-212, 215-216, 219, 225-226, 250-253, and 258 are rejected under 35 U.S.C. 103(a) as being made obvious by Doyle et al. (Proceedings of the 23rd Annual EMBS International Conference, Istanbul, Turkey, Oct. 2001, p.1-4), in view of Galley et al. (US 2003/0028089, Filed Jul. 31, 2001).

Doyle et al teach a control method for adjusting the insulin dosage schedule of an individual, wherein the dosage and timing of insulin is estimated based upon patient history and desirable glucose levels. Furthermore, Doyle et al teach a method wherein the glucose

response to at least one meal is observed and then used in conjunction with the patient's insulin sensitivity and initial dose of insulin to estimate the pre-prandial dosage and timing of insulin for the following day's meal (i.e. meal insulin), which may be equal to, or different from, the initial insulin dose. Doyle et al. teach equations that correlate timing and quantity of insulin injection, maximum/minimum glucose values Gmax and Gmin (i.e. feedback correction values) that vary between positive and negative [p.2, Col. 1, Section B]. Doyle et al also teach that the corrections in insulin dosage are based upon the post-prandial (i.e. after meal) glucose measurements from the previous day and also take into account caloric differences among the meals and timing of insulin [Section IIB and IIC]. Doyle et al further teach a method wherein the maximum glucose levels following each meal are maintained in the normal glycemic range, and progressively improve (i.e., optimize over time) and converge to provide an insulin profile (i.e., a predetermined target range) [Section IIIB]. In addition to the above-described method, Doyle et al also teach a method wherein the above steps are repeated during a 24-hour period, during which meals are ingested at variable times during the period, wherein meals are ingested more than 3 times during the day or fewer than three times during the day. Furthermore, Doyle et al teach that this method can be used either in a continuous fashion for constant fine-tuning, or on a periodic basis to allow re-calibration wherein the amount and timing of insulin delivery is updated (i.e., feedback control) [Section IIIA].

Doyle et al do not specifically teach a method wherein insulin dosage corrections incorporate the carbohydrate content of a meal, or measurements obtained from a blood glucose test.

Galley et al. teach a diabetes management system comprising an insulin delivery unit, a control unit, and a glucose sensor, for determining corrective insulin dosages when predictive glucose values lie outside of pre-determined ranges for calculating precise amounts of insulin

required to keep a user's blood sugar concentration at a previously set target [Abstract]. More specifically, Galley et al. teach additional intervention boluses (i.e. additional dosage) and delivered insulin in response to blood glucose values (i.e. corrective doses) [Fig. 5] and [0026]. Galley et al. also provide means for blood glucose testing and blood sample collection [0028]. Galley et al. also teach feed-back and feed-forward algorithms and equations for calculating insulin dosages based on carbohydrate-to-insulin ratios, scaling factors, total insulin dosage, carbohydrates, insulin-to-carbohydrate ratio, and linear fit intercept values (i.e. statistical correlation values) [Fig. 7], [0009], and [0063-0069]. Galley et al. also teach infusion rate constraints based on fractional values (β) and basal rates [0070-0072]. Galley et al. also teach a feedback algorithm expressed as a function of basal insulin, normalized insulin values (i.e. ratios), meal-related insulin doses, recommended insulin doses, target blood glucose values, sensitivity factors, time intervals between insulin cycles [0034] and [0040-0055], and related summation equations [p. 4, Col. 2, Equations 1, 2, and 3]. Galley et al. also teach user-input carbohydrate amounts, meal types, and glycemic indexes [0069], and fractional infusion rates (i.e. derivate) [0070-0071].

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the control method disclosed by Doyle et al. by incorporating additional parameters beneficially taught and provided by Galley et al., as meal size and duration cause variation in blood glucose levels and thus are important factors in determining the appropriate amount and timing of pre-meal and post-meal insulin dosing, as taught by Galley et al. [0021]. One would have been motivated to incorporate the teachings of Galley et al. into the glucose control method taught by Doyle et al. so as to derive the optimal dosage of insulin to provide both the basal insulin requirement and the meal-related insulin dosing of an individual for the expected benefit of improving patient control over blood glucose levels and

preventing postprandial hyperglycemia, a risk factor for coronary heart disease in diabetic patients. One of skill in the art would have had a reasonable expectation of successfully combining the method of Doyle et al. with the parameters of Galley et al. as both teach methods for insulin dosage and blood glucose monitoring.

Response to Arguments

Applicant's arguments filed 09/06/2007 that Doyle et al. does not teach Basal Insulin or re-calculating constants within its program for each use have been fully considered but are not persuasive. Doyle et al (p.2, Section B) shows manipulated variables (i.e. timing and quantity of insulin injection) and controlled variables (i.e. maximum and minimum glucose values) corresponding to quality values that are exactly the type of variables that a medical professional would use to evaluate the efficiency of a particular insulin regimen, which at a minimum is suggestive of basal insulin values. Doyle et al. also show (p.3, Section A) their regiment could be used either in a continuous fashion for constant re-tuning or on a periodic basis to allow re-calibration. This rejection is therefore maintained.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley
Patent Examiner
Art Unit 1631
Office: 571-272-4425
Direct Fax: 571-273-4425

/John S. Brusca/
Primary Examiner
Art Unit 1631